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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,493	03/04/2002	Thomas Raschke	04035.244910	6041

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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/05/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*file copy***Application No.**

10/090,493

Applicant(s)

RASCHKE ET AL.

Examiner

JYOTHSNA A VENKAT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Receipt is acknowledged of extension of time, amendment A, declaration and IDS filed on 4/22/03. Claims 1-14 are pending in the application and the status of the application is as follows:

The following rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 6,419,946B1 ('946) and U. S. Patent 5,985,296 ('296) .

The instant application is claiming composition or oil in water emulsion comprising:

1. *Inclusion complexes of retinoids with cyclodextrin and the species is retinal gamma cyclodextrin complex.*

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2. one or more neutralized esters of one or more monoglycerides, diglycerides, or both, of one or more saturated fatty acids with citric acid. The species is glyceryl stearyl citrate.

The patent '946 teaches component 2 in cosmetic composition as a surfactant in the form of emulsions. See the abstract, see col.3, lines 5-20 and see lines 37-38 for the species and see the range at lines 45-46. see also col.7 and the example. The patent does not teach component 1. However the patent '296 teaches component 2 at col.2, lines 40 et seq and the species in cosmetic formulations at col.3, lines 5-30 and at lines 53-55 teaches that surfactants can be added to the cosmetic compositions.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of '296 and combine it with the *glyceryl stearylcitrate* of '946, expecting beneficial effect to the hair. The motivation to use the *glyceryl stearylcitrate* stems from the teachings of '946 that the emulsions are stable on storage and have good cosmetic properties and the compound *glyceryl stearylcitrate* itself acts as a surfactant and therefore can be used in compositions without using any other surfactant. The idea of combining the ingredients flows logically from the art for having been used individually in cosmetic compositions. This is a prima facie case of obvious ness.

Arguments

4. Applicant's arguments filed 4/22/03 have been fully considered but they are not persuasive..

Applicant's argue that the patent '946 does not suggest the addition of retinol or its derivatives, much less retinol or its derivatives stabilized with cyclodextrin to the nanoemulsions

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and the patent does not teach or suggest that the claimed combination can exhibit synergistic effect in increasing the stability of such compounds against chemical degradation.

Applicants argue that that the '296 patent does not recognize the synergistic stabilizing effect of the claimed combination and when read in entirety for all that it fairly suggests, the '296 patent teaches away from the use of additional stabilizing agents at column 2, line 61 through column 3, line 7.

5. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '296 patent teaches at col.3, lines 53-55 that surfactants can be added to the compositions containing these retinol-cyclodextrin complexes. The patent '946 teaches the use of citrate esters, in nanoemulsions, which are stable on storage, and has good cosmetic properties. Nanoemulsions are oil-in-water emulsions. Applicant's examples are drawn to creams, which are one form of nano-emulsions/oil-in water-emulsions. One of ordinary skill in the art would be motivated to use citrate esters in retinol-cyclodextrin complex compositions with a reasonable expectation of success knowing that the compositions has better shelf life.

6. The declaration under 37 CFR 1.132 filed 4/22/03 is insufficient to overcome the rejection of claims 1-14 based upon the combination of the patents '296 and '946as set forth in the last Office action because: of the following reasons

I. The declaration is not commensurate with the scope of the claims.

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II. The declaration is with respect to *scope of claim 6*. However the test results are not compared under identical conditions. The **glyceryl stearate citrate** weight in example 1 is 2% where as in the comparative it is 6.50%. The same is true for retinol-cyclodextrin complex. In the example 1 it is 0.44% where as in the comparative example it is 0.19%. The declaration therefore is insufficient.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT whose telephone number is 703-308-2439. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 703-308-2927. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


JYOTHSNA A VENKAT
Primary Examiner
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June 3, 2003